K102875

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name and Address:

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DEC 2 0 2010

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Date Summary was Prepared: December 17, 2010

Trade Names: Camino 110-4B OLM Intracranial Pressure Monitoring Kit (Camino 110-4B)
Camino 110-4BT Intracranial Pressure-Temperature Monitoring Kit (Camino 110-4BT)
Camino 110-4G Post Craniotomy Subdural Pressure Monitoring Kit (Camino 110-4G)
Camino 110-4L Intracranial Pressure Monitoring Catheter with Licox®*IMC* Bolt Fitting (Camino 110-4L)

Common Name:	Intracranial Pressure and Pressure-Temperature Monitoring Kits
Classification:	Device, Monitoring, Intracranial Pressure
Device Class:	Class II, under 21 CFR 882.1620
Classification Panel:	Neurology
Product Code:	GWM

Predicate Devices: K853864 Intracranial Pressure Monitoring Kit, Model 070 (Camino 110-4B and Camino 110-4G)
K962928 Combined Intracranial Pressure-Temperature Sensing (Camino 110-4BT)
K022553 Camino® Intracranial Pressure Monitoring Catheter with *LICOX® IMC* Bolt Fitting, Model 110-4L (Camino 110-4L)

Device Description:

The Camino 110-4 Intracranial Pressure Monitoring catheters are sterile transducer-tipped pressure or pressure/temperature monitoring catheters that are used by neurosurgeons to

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rapidly determine and continuously monitor intracranial pressure or pressure/temperature. The Camino 110-4B is used for Intraparenchymal Pressure Monitoring and the Camino 110-4BT is used to simultaneously measure intracranial pressure and temperature in the parenchyma. The Camino 110-4G is used for Post Craniotomy Subdural Pressure Monitoring, and the Camino 110-4L is intended for use with the Licox Brain Oxygen Monitoring System to measure intracranial pressure in the parenchyma.

The primary issues affecting the safety of passive implants in the MR environment concern radio frequency (RF) heating, magnetically induced displacement force and torque, and image artifacts. Verification testing was performed in each of these areas to determine the effects of the MR environment on the Camino 110-4B, 110-4BT, 110-4G, and 110-4L catheters. The devices were tested under best and worst case heating conditions in a 1.5 Tesla (T) MRI environment, in accordance with **ASTM Standard 2182-02a *"Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"***. Testing was also performed to determine the magnetically induced displacement force and magnetically induced torque exerted on these devices in accordance with **ASTM F2052-06 *"Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"*** and **ASTM F2213-06 *"Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"***. In addition, artifact images were provided for these devices in accordance with **ASTM F2119 *"Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"***.

Based on a risk/benefit analysis for the Camino 110-4B, 110-4BT, 110-4G, and 110-4L, it was determined that the potential risk of injury to the patient due to the high heating potential under certain conditions in an MR environment does not outweigh the clinical benefit derived from MRI images. Therefore, Integra has labeled these devices as MR Unsafe.

The proposed Camino devices are identical to their respective predicate devices, except for the addition of MR Safety Information to the current labeling. The addition of MRI Safety information to the labeling is intended to improve the safe use of the Camino 110-4B, Camino 110-4BT, Camino 110-4G, and Camino 110-4L catheters by clarifying to healthcare providers in a clear and concise manner that the devices are MR Unsafe.

Indications for Use:

Camino 110-4B OLM Intracranial Pressure Monitoring Kit

The use of the OLM Intracranial Pressure Monitoring Kit by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure in the parenchyma or the subarachnoid space, is clinically important.

Camino 110-4BT Intracranial Pressure-Temperature Monitoring Kit

The Camino Intracranial Pressure Temperature Monitoring Kit is indicated for use by qualified neurosurgeons for measurement of intracranial pressure and temperature in the parenchyma.

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Camino 110-4G Post Craniotomy Subdural Pressure Monitoring Kit:

The use of the Post Craniotomy Subdural Pressure Monitoring Catheter by a qualified neurosurgeon is indicated when direct pressure measurement subdural space, post craniotomy, is clinically important.

Camino 110-4L Intracranial Pressure Monitoring Catheter with Licox®*IMC* Bolt Fitting

The Camino® Intracranial Pressure Monitoring Catheter with Licox IMC Bolt Fitting, Model 110-4L is indicated for use by a qualified Neurosurgeon when direct measurement of intracranial pressure in the parenchyma or subarachnoid space is clinically important. The Camino® Intracranial Pressure Monitoring Catheter with Licox IMC Bolt Fitting, Model 110-4L is intended to be used only through a Licox Brain Oxygen Monitoring System Bolt.

Substantial Equivalence:

The proposed Camino 110-4B, Camino 110-4BT, Camino 110-4G, and Camino 110-4L catheters have identical Indications For Use, and are intended for the same target population as the currently cleared and marketed Camino 110-4B, Camino 110-4BT, Camino 110-4G, and Camino 110-4L catheters. The proposed catheters and accessories are identical to their respective predicates in function, manufacturing processes, sterilization processes, and packaging configurations. The proposed devices incorporate the same basic designs, utilize the same operating principles, have identical performance specifications, and consist of identical implanted materials as their respective predicates.

The only difference between the proposed Camino 110-4B, Camino 110-4BT, Camino 110-4G, and Camino 110-4L catheters is the addition of MRI Safety Information to the labeling. The proposed labeling is similar to the current labeling, with the only difference being the addition MR Unsafe information to the labels and Directions for Use. The addition of MRI Safety Information to the proposed labeling does not negatively impact the safety and efficacy of the proposed devices, and in fact, is being added to the labeling in order to improve the safe and effective use of the devices in the MR environment by clarifying to clinicians, MR Technicians, and Radiologists that the devices are MR Unsafe.

The addition of MRI safety information to the labeling does not alter the indications for use or the fundamental scientific technology of the devices. The Camino 110-4B is substantially equivalent to the current Camino 110-4B. The Camino 110-4BT catheter is substantially equivalent to the current Camino 110-4BT. The Camino 110-4G catheter is substantially equivalent to the current Camino 110-4G catheter. The Camino 110-4L catheter is substantially equivalent to the current Camino 110-4L catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra LifeSciences Corporation
c/o Ms. Donna Millisky
Regulatory Associate II
311 Enterprise Drive
Plainsboro, NJ 08536

DEC 2 0 2010

Re: K102875
Trade/Device Name: Camino 110-4B OLM Intracranial Pressure Monitoring Kit
Camino 111-4G Post Craniotomy Subdural Pressure Monitoring Kit
Camino 110-4BT Intracranial Pressure-Temperature Monitoring Kit
Camino 110-4L Intracranial Pressure Monitoring Catheter with Licox IMC Bolt Fitting
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: September 30, 2010
Received: October 1, 2010

Dear Ms. Millisky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

DEC 2 0 2010

510(k) Number:

Device Name: Camino 110-4B OLM Intracranial Pressure Monitoring Kit

Indications for Use:

The use of the OLM Intracranial Pressure Monitoring Kit by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure in the parenchyma or the subarachnoid space, is clinically important.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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INDICATIONS FOR USE STATEMENT

DEC 2 0 2010

510(k) Number:

Device Name: Camino 110-4G Post Craniotomy Subdural Pressure Monitoring Kit

Indications for Use:

The use of the Post Craniotomy Subdural Pressure Monitoring Catheter by a qualified neurosurgeon is indicated when direct pressure measurement in the subdural space, post craniotomy, is clinically important.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

X
Prescription Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102875

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INDICATIONS FOR USE STATEMENT

DEC 2 0 2010

510(k) Number:

Device Name: Camino 110-4BT Intracranial Pressure-Temperature Monitoring Kit

Indications for Use:

The Camino Intracranial Pressure Temperature Monitoring Kit is indicated for use by qualified neurosurgeons for measurement of intracranial pressure and temperature in the parenchyma.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K102875

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INDICATIONS FOR USE STATEMENT

DEC 2 0 2010

510(k) Number:

Device Name: Camino 110-4L Intracranial Pressure Monitoring Cather with Licox®*IMC* Bolt Fitting

Indications for Use:

The Camino® Intracranial Pressure Monitoring Catheter with Licox IMC Bolt Fitting, Model 110-4L is indicated for use by a qualified Neurosurgeon when direct measurement of intracranial pressure in the parenchyma or subarachnoid space is clinically important. The Camino® Intracranial Pressure Monitoring Catheter with Licox IMC Bolt Fitting, Model 110-4L is intended to be used only through a Licox Brain Oxygen Monitoring System Bolt.

Prescription Use ___X___ **AND/OR** **Over-The-Counter-Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102875